

NOVO NORDISK A S
Form 6-K
June 22, 2004

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Issuer Pursuant to Rule 13a-16 or 15d-16

of the Securities Exchange Act of 1934

22 June 2004

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

**Novo Allé
DK- 2880, Bagsvaerd
Denmark**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F

Form 20-F ☒ Form 40-F ☐

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐ No ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b):82-_____

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf of the undersigned, thereunto duly authorized.

Date: 22 June 2004

NOVO NORDISK A/S

Lars Rebien Sørensen, President and Chief Executive Officer

Stock Exchange Announcement

22 June 2004

New breakthrough for NovoSeven®

NovoSeven® effective in treatment of intracerebral haemorrhage

Novo Nordisk today announced the first results from the largest clinical trial ever conducted with a pharmaceutical agent in the treatment of intracerebral haemorrhage (ICH). The phase 2b study demonstrated that treatment with NovoSeven® of ICH patients led to a significant reduction in haematoma growth compared to the placebo group.

Importantly, results demonstrated that patients treated with NovoSeven® had significantly improved neurological and functional outcome, implying a lasting patient benefit in terms of reduced disability and dependency on help. This is the first time such encouraging results have been observed in any ICH trial.

The study showed that treatment with NovoSeven® for ICH was associated with a minor, non-significant increase in thromboembolic events that was vastly outweighed by highly significant clinical benefits across the trial.

Lars Rebien Sørensen, president and chief executive officer of Novo Nordisk, said: "The proof of concept for the use of NovoSeven® in the treatment of intracerebral haemorrhage represents a pioneering breakthrough. It is a major step forward in our aspiration to develop NovoSeven® as a general treatment of critical bleedings. This is an extraordinary extension of the positive results obtained in the treatment of trauma victims late last year."

Based on the data, Novo Nordisk will immediately liaise with regulatory agencies in the effort to achieve approval for the use of NovoSeven® as the first pharmaceutical treatment of ICH.

The ICH study involved 400 patients in 20 countries, in a multi-centre, randomised, double-blind, placebo-controlled dose-response study. Patients who all had spontaneous ICH confirmed by Computed Tomography (CT) scan within three hours of symptom onset, were randomised to receive either NovoSeven® or placebo, in addition to conventional treatment.

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CVR Number:
24256790

The above scientific results do not change Novo Nordisk's expectations for the financial results for 2004.

PRESENTATION OF THE KEY RESULTS

At 14:00 CET today, corresponding to 13:00 UK time and 8:00 am New York time, a brief conference call about the findings of the study will be held. The number of the conference call is +44 20 7162 0188 / +1 334 323 6203 and the password is Novo Nordisk. If you have any problem assessing the conference call, call Novo Nordisk Investor Relations Coordinator Kazuko Kjeldsen at +45 4442 6035 or +45 3079 6035. Investors will also be able to listen in via a link on novonordisk.com, which can be found under 'Investors - Conference call'. Presentation material for the conference call will be made available immediately before the conference on the same page.

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On Saturday 26 June 2004 the key results from the study will be presented at the 5th World Stroke Congress in Vancouver, Canada. For further information with regard to the conference, please visit www.kenes.com/stroke2004/. A short summary of the presentation will be made available on novonordisk.com under 'Investors' on Monday 28 June 2004.

ABOUT INTRACEREBRAL HAEMORRHAGE

Studies indicate that each year around 250,000 people in North America, Europe and Japan experience an Intracerebral Haemorrhage (ICH), also known as haemorrhagic stroke. ICH is the most deadly and least treatable form of stroke. In Western and Asian populations, ICH constitutes 15 and 30% of all stroke cases, respectively. ICH patients face the highest rates of mortality or severe disability of all stroke victims and until now, no proven ICH treatment has been identified. Those patients who survive an ICH are left with more severe disabilities and complications than survivors of other forms of stroke¹, including - often total - loss of movement, speech and mental capability.

When ICH has been confirmed by a CT scan, recognised treatment options are severely limited in number and treatment is only symptomatic. Certain types of ICH are attempted treated by surgical removal, depending on the location of the haemorrhage within the brain. However, this approach has so far been without proven benefit and furthermore, there is a serious risk of renewed haemorrhaging at the ICH site, as well as brain damage from the surgery itself. Treatment of ICH patients therefore remains supportive and overall outcomes poor¹.

ABOUT NOVOSEVEN® AND INTRACEREBRAL HAEMORRHAGE

NovoSeven® is a recombinant haemostatic agent (recombinant activated factor VII). The product is currently registered for treatment of bleeding episodes in haemophilia patients with congenital or acquired inhibitors against the clotting factors VIII or IX. Its unique mechanism of action induces haemostasis independently of FVIII and FIX. By stimulating a burst of thrombin production on the surface of activated platelets, rFVIIa is able to accelerate and strengthen the body's own clotting process. Factor Xa, in complex with other factors, then converts prothrombin to thrombin, which leads to the formation of a haemostatic plug by converting fibrinogen to fibrin and thereby inducing local haemostasis.

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NovoSeven® travels to the ICH site through the circulation and reaches ruptured vessels in the brain without invasive surgery. At the location of ICH, NovoSeven® accelerates the coagulation process from within. In this way, NovoSeven® can limit the haematoma (blood leakage) size, which is a vital predictor of outcome for ICH patients. Smaller haematomas are less damaging to the brain, and are related to better clinical outcomes for patients.

FORWARD-LOOKING STATEMENT

The above sections contain forward-looking statements as the term is defined in the US Private Securities Litigation Reform Act of 1995. Forward-looking statements provide current expectations or forecasts of events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk's products, introduction of competing products, Novo Nordisk's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Risks and uncertainties are further described in reports filed by Novo Nordisk with the US Securities and Exchange Commission (SEC) including the company's Form 20-F, which was filed on 27 February 2004. Please also refer to the section 'Management of risk in Novo Nordisk' in the Annual Financial Report 2003. Novo Nordisk is under no duty to update any of the forward-looking statements or to conform such statements to actual results, unless required by law.

Novo Nordisk is a healthcare company and a world leader in diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. With headquarters in Denmark, Novo Nordisk employs approximately 18,800 full-time employees in 69 countries, and markets its products in 179 countries. Novo Nordisk's B shares are listed on the stock exchanges in Copenhagen and

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London. Its ADRs are listed on the New York Stock Exchange under the symbol 'NVO'. For more information, visit novonordisk.com.

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ⁱ Mayer. Stroke 2003; 34:224-229.

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